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No. 03-779

IN THE

Supreme Court of the United States

ANDRX PHARMACEUTICALS, INC.,

Petitioner,

—v.—

THE KROGER CO., ALBERTSON'S, INC., HY-VEE, INC., THE STOP & SHOP SUPERMARKET CO., WALGREEN CO., ECKERD CORP., CVS MERIDIAN, INC., and RITE AID CORP., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

I. The Federal Trade Commission's Recent Decision Demonstrates the Need for This Court's Review Now 2

II. The Circuit Split Is Having Nationwide Effects 2

III. There Is No Reason to Prolong the Circuit Split Pending Trials of Collateral Issues 4

IV. The Legislation Plaintiffs Cite Is Wholly Irrelevant 6

V. The Issue Is Ripe For Review 7

VI. The Circuit Split Concerns Fundamental Principles 7

A. The Appropriate Scope of Antitrust Review 7

B. The Significance of Patent Ownership 9

CONCLUSION 10

TABLE OF AUTHORITIES

Cases

Arizona v. Maricopa County Med. Soc'y, 457 U.S. 332 (1982) 5

Beneficial Nat'l Bank v. Anderson, ___ U.S. ___, 123 S. Ct. 2058 (2003) 5

Breuer v. Jim's Concrete of Brevard, Inc., 538 U.S. 691 (2003) 5

Cal. Dental Ass'n v. FTC, 526 U.S. 756 (1999) 2, 8

Catalano, Inc. v. Target Sales, Inc., 446 U.S. 643 (1980) 5

Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972) 10

EEOC v. Waffle House, Inc., 534 U.S. 279 (2002) 4

FTC v. Cement Inst., 333 U.S. 683 (1948) 2, 7

In re Cardizem CD Antitrust Litig., 99 MDL 1278, Order No. 80, slip op. (E.D. Mich. Nov. 13, 2003) 6

Nat'l Collegiate Athletic Ass'n v. Board of Regents, 468 U.S. 85 (1984) 2

NYNEX Corp. v. Discon, Inc., 525 U.S. 128 (1998) 8

Polymer Tech., Inc. v. Bridwell, 103 F.3d 970 (Fed. Cir. 1996) 10

State Oil Co. v. Khan, 522 U.S. 3 (1997) 6, 8

Statutes

15 U.S.C. § 22 3

15 U.S.C. § 45 3

28 U.S.C. § 1292 5

35 U.S.C. § 154 10

Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173 6

Other Authorities

66 Fed. Reg. 18636 (2001) 6, 9

Appellees' Petition for Rehearing En Banc, *Valley Drug Co. v. Abbott Labs.* (11th Cir. 2003) (No. 02-12091-J) 1, 2

David A. Balto & Michael Gallagher, *Recent Developments in Patent Settlement Litigation*, 1 Antitrust Rep. 39 (Fall 2003) 7, 8

Robert L. Stern *et al.*, Supreme Court Practice (8th ed. 2002) 5

Respondents (Plaintiffs) concede a circuit split. Opp. 17-18. The Eleventh Circuit rejected the Sixth Circuit's characterization of a patent settlement as illegal *per se* under the antitrust laws and declared intellectual property settlements legal, provided that they restrain competition no more than a court might. Pet. 12.

Only three months ago, Plaintiffs (who are also plaintiffs in the Eleventh Circuit) viewed the need to resolve this split as one of "exceptional" and "vital public importance." Appellees' Pet. for Reh'g at i, 2, *Valley Drug Co. v. Abbott Labs.* (11th Cir. 2003) (No. 02-12091-J). They warned that the Eleventh Circuit's rule of reason analysis would "halt . . . imminent competition" against "brand-name drugs with annual sales of more than $20 billion" and "legitimize the use of similar" agreements. *Id.* at 2. Their new position that the split is unimportant lacks credibility.

Plaintiffs' position now, that the *Sixth Circuit* applied a rule of reason analysis to the Stipulation's effects and benefits, is contradicted by the Sixth Circuit's express holding that any analysis of competitive effects or benefits was "irrelevant." Pet. App. 20a. It is further refuted by the Eleventh Circuit, Federal Trade Commission (FTC), each of the five *amici* here, and every academic, all of whom have read the decision as a *per se* ruling (with some supporting *per se* treatment and others opposing it). See, *infra*, pp. 7-9.

Plaintiffs' arguments for delay are equally meritless. This Court created the *per se* category of antitrust analysis. Because of its extraordinary force when imposed, this Court has frequently reached out to clarify its applicability to new types of agreements or circumstances. If anything, review now is more timely given the Sixth Circuit's *per se* condemnation on summary judgment. The Sixth Circuit's *per se* characterization is not only dispositive of the legality issue in this case; the circuit split is having a real effect on intellectual property settlements and licenses nationwide. As explained in the *amicus* briefs of two major intellectual property bar associations with over 15,000 members, lawyers

throughout the country have no choice but to advise their clients that, in every instance where Sixth Circuit law might apply, the *per se* ban affects "all patent settlements and license agreements in all industries." See, *infra*, p. 3. This Court's review is urgently needed.

I. The Federal Trade Commission's Recent Decision Demonstrates the Need for This Court's Review Now

This Court relies on the FTC for its expert views of the antitrust laws. *See FTC v. Cement Inst.*, 333 U.S. 683, 720 (1948). Although Plaintiffs invoke an FTC decision rendered after Andrx petitioned for *certiorari* (Opp. 13-15), they do not advise that the FTC explicitly *rejected* the Sixth Circuit's *per se* approach: In an extraordinary statement, the FTC held: "**We . . . do not believe the [Sixth Circuit's] opinion has taken adequate account of Supreme Court decisions that mandate a more nuanced approach.**" *In re Schering-Plough Corp.*, No. 9297, Comm'n Op. at 13 & n.26 (FTC Dec. 18, 2003) (available at www.ftc.gov/os/adjpro/d9297/031218commissionopinion.pdf) ("*Schering*") (citing *Cal. Dental Ass'n v. FTC*, 526 U.S. 756 (1999); *Nat'l Collegiate Athletic Ass'n v. Board of Regents*, 468 U.S. 85 (1984)) (emphasis added). Addressing the circuit split, the FTC emphasized that antitrust challenges to patent settlements raise "important policy issues at the intersection of patent law and antitrust law." *Schering* at 1. Contrary to Plaintiffs' claim, the FTC recognized that the issue will recur and that its decision "would have an impact not only on this particular case but also on other antitrust cases before the Commission and the courts that involve the legality of patent settlements." *Id.* at 1, 30.

II. The Circuit Split Is Having Nationwide Effects

Plaintiffs wrongly assert that the direct conflict in the circuits is unimportant because it "only" concerns two circuits. Opp. 17. Plaintiffs ignore the Sixth Circuit's "conflict with the Federal Circuit's case law," Amicus Br. of American Intellectual Property Law Ass'n ("AIPLA Amicus Br.") at 2, 11, the multidistrict nature of the litigation

affected by the conflict (Pet. 18-19), and, most significantly, the fact that "[a]ny nationwide company that does business within the Sixth Circuit can be sued there and . . . made subject to its rule." Amicus Br. of Washington Legal Foundation ("WLF Amicus Br.") at 15.

The antitrust laws provide ample opportunities to choose a forum, and an explicit conflict between circuits on the critical question of whether a practice is *per se* illegal or subject to the rule of reason is an open invitation to parties to select a forum on that basis. Under the antitrust laws' nationwide jurisdiction provision, a plaintiff may sue "in any district wherein [the defendant] may be found or transacts business." 15 U.S.C. § 22. Thus, if the conflict is not resolved by this Court, plaintiffs seeking damages from the many corporations that do business throughout the country will flock to the district courts of the Sixth Circuit. By contrast, parties facing an adverse FTC determination (such as *Schering*) will likely seek review in the Eleventh Circuit. *See* 15 U.S.C. § 45(c) (jurisdiction to review FTC order lies in any circuit where challenged practice was used or corporation carries on business).

Plaintiffs' contention that the conflict in the circuits will affect only the pharmaceutical industry is also unpersuasive. Opp. 23-24. The situation would be untenable even were Plaintiffs correct, but they are plainly not. Nothing in the logic of the Sixth Circuit's decision is so limited, as explained in the amicus briefs of the two pre-eminent intellectual property bar associations. That is why the American Intellectual Property Lawyers' Association has represented to the Court that its members now routinely advise clients (pharmaceutical or not) that "the Sixth Circuit's *per se* rule extends to **all** patent settlements and license agreements in **all** industries." *See* AIPLA Amicus Br. at 1 (emphasis added); *id.* at 7-8. For AIPLA's 15,000 members (AIPLA Motion at 1), the ruling "introduces enormous uncertainty into routine agreements." AIPLA Amicus Br. at 6. They predict "[a] corresponding reduction

in the number of patent settlements and licenses" with significant economic repercussions. *Id.* at 9.

Their concern is driven by the absence of any logical distinction between the cash payment condemned by the Sixth Circuit and other forms of consideration, such as routine waivers of accrued damages or future licenses. *See* Pet. 16-18. Despite Plaintiffs' *ipse dixit* that such consideration may be lawful (Opp. 9 n.4), the Sixth Circuit did not limit its holding to cash payments or interim settlements. Its rationale necessarily implies that **any** consideration will unlawfully "bolster" a patent's power. *See* Amicus Br. of N.Y. Intellectual Property Law Ass'n ("NYIPLA Amicus Br.") at 13 ("Sixth Circuit provided no rationale for distinguishing between" the settlements it addressed and other agreements). Indeed, even Plaintiffs have argued that licenses and settlements are anticompetitive. Brief of Individual Sherman Act Plaintiffs-Appellees at 36-38 n.19, *In re Cardizem CD Antitrust Litig.*, (6th Cir. 2003) (No. 00-2483) ("Pl. 6th Cir. Br."). Most significantly, lawyers read the Sixth Circuit decision as indicating that "any type of consideration flowing from a patentee to a potential infringer as part of the overall agreement would render the agreement *per se* illegal." AIPLA Amicus Br. at 1. These practitioners face "confusion" "as they struggle to counsel their clients" regarding the legality of otherwise standard patent settlements and licenses "while the conflict remains unresolved." NYIPLA Amicus Br. at 5; *id.* at 8-15.

III. There Is No Reason to Prolong the Circuit Split Pending Trials of Collateral Issues

That the Sixth Circuit found *per se* illegality on summary judgment (*see* Opp. 21-23) is surely not a reason to ignore the circuit split. *See, e.g., EEOC v. Waffle House, Inc.*, 534 U.S. 279, 284-85 (2002) (reversing pretrial interlocutory decision concerning ability to recover non-injunctive relief).

The Sixth Circuit found Andrx's conduct illegal based on a determination that *per se* condemnation rather than rule

of reason review governs the Stipulation. Such a fundamental and broad ruling on antitrust liability is one that this Court has historically considered on an interlocutory basis. *See, e.g., Arizona v. Maricopa County Med. Soc'y*, 457 U.S. 332, 336-37 (1982) (granting review of order certified under 28 U.S.C. § 1292(b) to determine whether *per se* doctrine or rule of reason should govern); *Catalano, Inc. v. Target Sales, Inc.*, 446 U.S. 643, 643-44 (1980) (same). Further proceedings below will not amplify the record on the legality of the Stipulation because the lower courts cut off any inquiry through discovery and trial into the actual benefits of the Stipulation. *See* Pet. App. 50a. The intellectual property bar and pharmaceutical manufacturers need immediate guidance from this Court regarding the proper antitrust analysis to be employed. *See, e.g.*, NYIPLA Amicus Br. at 2-3.

Review is appropriate because the question presented is "an important and clear-cut issue of law," on which the circuits are cleanly divided, that is "fundamental to the further conduct" of several trials that this multidistrict litigation will produce. *See* Robert L. Stern *et al.*, Supreme Court Practice § 4.18 at 259 (8th ed. 2002).[1] Indeed, where, as here, an interlocutory appeal is certified under 28 U.S.C. § 1292(b), the nonfinal nature of the order should not delay review, as the certification itself "incorporates some of the considerations relevant to the Court in deciding whether to review any nonfinal judgment." *Id.* § 4.19 at 261; *see, e.g.*, *Beneficial Nat'l Bank v. Anderson*, ___ U.S. ___, 123 S. Ct. 2058, 2061 (2003); *Breuer v. Jim's Concrete of Brevard, Inc.*, 538 U.S. 691, ___, 123 S. Ct. 1882, 1884 (2003).

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[1] Contrary to Plaintiffs' implication (Opp. 22), only one case in this multidistrict litigation is tentatively scheduled for an April trial in Michigan. Another was just referred for remand to a district court in Florida (in the Eleventh Circuit) where it should be tried.

IV. The Legislation Plaintiffs Cite Is Wholly Irrelevant

Plaintiffs wrongly assert that the settlements at issue are a "thing of the past" (Opp. 25), claiming that recent legislation removes the incentive for entering into such agreements by providing for a "total forfeiture of the generic company's 180-day exclusivity period" within 75 days of entry of a settlement (Opp. 26).[2] In fact, the forfeiture provision Plaintiffs cite is wholly inapposite to the settlements at issue, will not deter future settlements (*see* Amicus Br. of Pharm. Research Mfrs. of America at 3 n.2), and is irrelevant to the antitrust issues here. Congress has not addressed and will not address the Sixth Circuit's *per se* ban; that is the province of this Court. Pet. 25; *see also State Oil Co. v. Khan*, 522 U.S. 3, 21 (1997) (Court does not leave Sherman Act changes to Congress because courts are expected "to give shape to the statute's broad mandate by drawing on common-law tradition").

The legislation Plaintiffs cite is triggered only if "**a court signs a settlement** order or consent decree **that enters a final judgment that includes a finding that the patent is invalid or not infringed**." Pub. L. No. 108-173 § 1102(a)(2) (emphasis added). Thus, typical settlements, entered into with no finding of wrongdoing, without court involvement, or on an interim basis, trigger no forfeiture. The FTC understood that these legislatives changes (which it

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[2] Since Plaintiffs do not seek damages based on any claim that Andrx delayed the sale of its reformulated product or would have relinquished any exclusivity right, *see In re Cardizem CD Antitrust Litig.*, 99 MDL 1278, Order No. 80, slip op. at 50 n.11 (E.D. Mich. Nov. 13, 2003), Plaintiffs' references to those issues (Opp. 4, 10 n.5) are red herrings. Similarly, the alleged "bottleneck" cited by Plaintiffs (*id.*) was a product of a subsequent change in law, not the Stipulation, and is not at issue here. *See* 66 Fed. Reg. 18636, 18637 (2001) (during the relevant time "the governing FDA regulations required that an ANDA applicant successfully defend the patent holder's suit in order to be entitled to this exclusivity").

commented on (*see* Opp. 26)) would not resolve the critical antitrust issues presented here. It emphasized the "increase in pioneer/generic patent litigation and . . . litigation settlements" that could be affected by its ruling. *Schering* at 1, 30. Another provision, facilitating FTC review of certain patent agreements, renders it "of critical importance to the patent community that the FTC . . . obtain the authoritative guidance of this Court" regarding how to evaluate such agreements. NYIPLA Amicus Br. at 18; *id.* at 8.

V. The Issue Is Ripe For Review

In addition to the FTC's expert views expressed in *Schering*, this Court has at its disposal the considered views of the scholars who have fully addressed whether intellectual property settlements should be subject to *per se* liability, with well over a dozen articles published over the past five years. *See, e.g.*, Pet. 28-29 & n.3 (citing articles); Opp. 9 n.4, 12 (same). As one of the commentators relied on by Plaintiffs recently stated in analyzing the split between the Sixth and Eleventh Circuits, "[p]robably few areas of antitrust law are the subject of as much antitrust litigation or academic commentary as the settlement of patent litigation in the pharmaceutical industry." David A. Balto & Michael Gallagher, *Recent Developments in Patent Settlement Litigation*, 1 Antitrust Rep. 39, 39 (Fall 2003) ("Balto"). "Percolation" is unlikely to produce new insights, and a delay in resolving the conflict will prejudice the many businesses that need certainty and uniformity in this area of the law.

VI. The Circuit Split Concerns Fundamental Principles

A. The Appropriate Scope of Antitrust Review

Recognizing that *per se* treatment in the context presented here is indefensible, Plaintiffs suggest that the Sixth Circuit's use of the *per se* label was mere semantics and that that court actually conducted a rule of reason review weighing procompetitive justifications, the "regulatory context" and the patent's "exclusionary power." *See* Opp. 1,

6, 11-12, 14; *id.* 9-10 (citing inapposite antitrust injury discussion).

Plaintiffs' strained and unpersuasive reading of the Sixth Circuit's decision is inconsistent with that of every objective reader, including the former FTC official relied on by Plaintiffs (Opp. 11 n.5), who stated that "by applying the per se rule, **the Sixth Circuit cut off any inquiry into the procompetitive benefits of the settlement, and, thus, did not address defendants' arguments on that topic**." Balto, 1 Antitrust Rep. at 44 (emphasis added); *see also* AIPLA Amicus Br. at 3 (Sixth Circuit "found the agreement *per se* illegal without considering the procompetitve justification").

In an antitrust case, the "essential inquiry" is "whether or not the challenged restraint enhances competition." *Cal. Dental*, 526 U.S. at 780. The Sixth Circuit used the *per se* characterization to jettison that entire inquiry as "irrelevant." Pet. App. 20a; *see* WLF Amicus Br. 6-9 (detailing distinction between *per se* and rule of reason analysis). The Eleventh Circuit, on the other hand, rejected both *per se* and rule of reason condemnation, holding that a patent settlement is lawful if the restraint imposed on the alleged infringer is no broader than a restraint the patentee could plausibly obtain from a court. Pet. App. 147a & n.27. The circuits thus reached opposite conclusions regarding a question that has historically warranted this Court's review, the appropriate contours of this Court's *per se* rule. *See, e.g., Cal. Dental*, 526 U.S. at 764-65; *NYNEX Corp. v. Discon, Inc.*, 525 U.S. 128, 133 (1998); *State Oil*, 522 U.S. at 9.

Far from conducting a rule of reason analysis, the Sixth Circuit bluntly held that Andrx's "claims that the [Stipulation] lacked anticompetitive effects and had procompetitive benefits are **simply irrelevant**." Pet. App. 20a (emphasis added). In applying the *per se* rule, the court "presume[d]" the Stipulation anticompetitive **without** "evaluat[ing] the **actual** anticompetitive effects or procompetitive justifications." Pet. App. 20a (emphasis added).

Thus, unlike *Schering*, where the FTC applied a rule of reason analysis examining the actual competitive effects after a full trial, the courts below condemned the Stipulation here before discovery, and before Andrx could engage experts in the case, let alone develop and proffer evidence of the Stipulation's actual effects. The lower courts adopted Plaintiffs' position – not even defended here – that "inquiry into the purpose or benefits" of the Stipulation is neither "warranted [nor] permitted" and "[a]ll attempts . . . to justify such an agreement as 'procompetitive' must be rejected." Pl. 6th Cir. Br. at 15;[3] *see* Pet. App. 19a-21a, 81a. As the FTC concluded, such a summary rejection of competitive effects and benefits is not a rule of reason analysis and creates a direct conflict in the circuits. *Schering* at 7, 12-13, 15, 29; *id.* at 13 n.26, 29 (rejecting *Cardizem*; requiring "more extensive analysis of competitive effects").

B. The Significance of Patent Ownership

Even Plaintiffs concede that the Sixth and Eleventh Circuits split over a "fundamental" issue that may be outcome determinative: the "scope of the exclusionary right actually granted by Congress in the patent law." *See* Opp. 17-18.[4] Plaintiffs seek to downplay that "fundamental" split by asserting that the circuits merely addressed interim settlements implicating "pretrial" patent exclusionary effects. Opp. 17-19. But as the *amici* understand, all settlements (final or interim) concerning unadjudicated patent rights implicate the issue of whether the exclusionary right flows from the patent grant or the judgment enforcing it.

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[3] Plaintiffs' present reliance on Professor Hovenkamp (Opp. 12) contradicts their prior position that his "general analysis of patent settlements is subject to serious criticism." Pl. 6th Cir. Br. at 36.

[4] Plaintiffs' reliance on cases addressing whether the antitrust laws must accommodate state law restrictions on competition (Opp. 16) is misplaced in light of their concession that antitrust law must accommodate federal patent law (Opp. 7). *See* Pet. 23.

The split acknowledged by Plaintiffs is important. Before the Sixth Circuit's decision, the intellectual property bar was confident that the patent grant itself entitled the patente owner to freedom from infringing competition. *See* AIPLA Amicus Br. 9-11. This position was grounded in the statutory "**right to exclude** others," 35 U.S.C. § 154(a)(1), which "provides the basis for affording the patentee . . . an award of damages" for infringement that "has already occurred" prior to a judicial adjudication, *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 522 (1972), as well as a preadjudication presumption that any infringement will lead to irreparable harm, *Polymer Tech., Inc. v. Bridwell*, 103 F.3d 970, 973, 976 (Fed. Cir. 1996). Plaintiffs view the Sixth Circuit decision as rejecting that position and holding that "[t]he reward actually granted by Congress to patent holders for their innovation is only *some probability* . . . of being able to exclude competitors." Opp. 12, 17-18. This view, which Plaintiffs contend was rejected by the Eleventh Circuit (Opp. 17-18), is of great importance to intellectual property owners who invested in property that they believe **is** theirs, not "probably" theirs. Even as mischaracterized by Plaintiffs, the circuit split cannot be viewed as narrow or trivial.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

Respectfully submitted,

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